

Appl. No. 10/507,214  
Amendment dated: February 5, 2009  
Reply to Final Rejection of: November 28, 2007

Therefore, while the United Kingdom Patents and Design Journal issued on 2 May 2001, this does NOT constitute publication of the content of GB 0106046.6. All that was published on 2 May 2001 was: (i) Applicant Name; (ii) Title; (iii) Filing date; and (iv) Application Number. As a consequence, GB 0106046.6 was NOT available to the public after being published by Applicant Name and Title in the Journal. It is therefore incorrect that the content of GB 0106046.6 was published on 2 May 2001. In fact, the earliest that GB 0106046.6 could have published is eighteen months from its filling date, i.e. 12 September 2002. That is the law in the United Kingdom. Accordingly, it is most respectfully requested that the rejection over GB 0106046.6 be withdrawn. Since GB 0106046.6 is clearly not available as a reference, this document will not be discussed further in this response and it should be withdrawn in the next Official Action.

However, it is appreciated that the rejection is also over WO 02/072449, in the alternative under 35 USC 102(a). Applicants wish to note that this reference is available under 35 USC 102(e) as of its international filing date which is March 11, 2002, since the requirements of amended 35 USC 102(e) have been met as set forth in MPEP § 706.02(f)(1)(c). Therefore this response will be limited to a discussion of the reference available under 35 USC 102(e). In this regard, all reference to page and line number in this response will refer to those in WO 02/072449.

WO 02/072449 is concerned with a canister suitable for use in metered dose inhalers and fitted with a metering valve characterised in that its walls are formed of a laminate comprising a first layer which is composed of a metal and a second layer which is composed of a strengthening material. The citation is therefore concerned with improving the mechanical properties of the walls of the canister by using a laminated material. This has nothing to do with the presently claimed invention which is directed to reducing the formation of nitrosamines in SEALS for a pharmaceutical dispensing apparatus. It is interesting to note that the assignee of the present application, Bepak plc., is identified as a supplier of commercially available suitable metering valves for the canister of the invention of the '449 application. This is set forth at the bottom of page 11 of the '499 application which just proceeds the citation relied upon in the discussion

Appl. No. 10/507,214  
Amendment dated: February 5, 2009  
Reply to Final Rejection of: November 28, 2007

of the primary reference in the rejection, see page 3 of the rejection where pages 12 to 13 are cited. Clearly, the cited pages relate to the prior art compositions which fail to suggest the presently claimed invention as admitted on page 3 which states that the primary reference fails to expressly disclose a cross-linking agents such as sulfur or a sulfur donating compound free of peroxide curing agents and a polysulphide accelerator derived from xanthic acid or a derivative thereof having an isopropyl group, with the polysulfphide being substantially free from nitrogen, phosphorous and metallic elements, wherein the elastomeric composition comprises up to 3 wt.% (1.5wt%) of the accelerator based on the total weight of the accelerator and polymer in the composition wherein the weight ratio of the accelerator to the cross-linking agent in the elastomeric composition is in the range of from 1:1 to 3:1 which forms part of the presently claimed invention.

In addition, there is no recognition of the problem solved by the present invention in the prior art, see MPEP § 2141.02 III. DISCOVERING SOURCE/CAUSE OF A PROBLEM IS PART OF "AS A WHOLE" INQUIRY "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). There is no suggestion of the problem in the primary reference and even under KSR, Applicants' specification may not be used as a teaching reference. As noted at page 16 of Applicants' specification, in the seal compositions according to the present invention the accelerator is typically almost totally consumed during the cross-linking reaction. This results in a cleaner rubber and the extractables are reduced. Typically, substantially no nitrosamines are generated during the cross-linking reaction. Furthermore, the composition according to the present invention show improved ageing characteristics compared with the convention Neoprene and Butyl rubber formulations. Most or substantially all of any by products resulting from the cross-linking reaction may be volatiles.

As previously noted, Applicants most respectfully submit that it is clear that the claims are directed to seal for a valve for a pharmaceutical dispensing device which includes a metered dose inhalers which must meet strict FDA standards to insure proper operation and free of contamination. Such contamination may come from the seals used in these devices. On the contrary, Kaszas relates to tire inner tubes, air bladders and the like. At column 9, lines 50-55 the use of the vulcanizate as an aerosol spray can linings is described but this is not a seal for a valve as presently claimed or a device containing such a valve.

Moreover, an important aspect of the invention is the curing system to produce the claimed vulcanisate which includes the following limitations:

As a cross-linking agent: *sulphur or a sulphur-donating compound, the cross-linking agent being free of peroxide curing agents.*

As an accelerator: *a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.*

More specifically, Kaszas relates to butyl elastomeric compositions for use in articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders (see column 1, lines 6 to 31). The curing system is discussed in column 8, lines 1 to 4, and comprises (i) metal oxide, (ii) sulphur, and (iii) at least one sulphur-based accelerator. Kaszas discloses the following accelerators: thiuram sulphides such as tetramethyl thiuram disulphide (TMTD), thiocarbamates such as zinc dimethyl thiocarbamates (ZDC) and the thiazyl and benzothiazyl compounds such as mercaptobenzothiazyl disulphide (MBTS) (see column 8, lines 10 to 18). The preferred accelerator is said to be tetramethyl thiuram disulphide (TMTD) (see also column 14, Table VI). The present application acknowledges the use of these known accelerators (see page 2 of the specification, lines 26-35).

As discussed on pages 3 and 4 of the of the present application, it has been found that tetramethyl thiuram disulphide (TMTD) (and also mercaptobenzothiazyl disulphide (MBTS)) is a precursor for the formation of nitrosamines, which are undesirable in seals for pharmaceutical dispensing devices. Thus, the use of these compounds in a curing system for use in the manufacture of a seal for a pharmaceutical dispenser device has this disadvantage (of course, there is no appreciation of this disadvantage in Kaszas since this document is not concerned with pharmaceutical dispenser devices). Furthermore, in most pharmaceutical applications, it is also necessary to extract or wash the cured elastomer in order to remove surface residues and by-products resulting from the cure reaction and moulding process. The aforementioned conventional cure/accelerator systems require relatively lengthy extraction times (typically 50 to 70 hours). Prolonged extraction times have been found to result in a deterioration in material properties.

The present invention solves these problems by the use of a cross-linking system in which:

*sulphur or a sulphur-donating compound is used as a cross-linking agent (the cross-linking agent being free of peroxide curing agents), and  
a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof is used as an accelerator.*

It is submitted that there is no teaching or suggestion of such a system in Kaszas. In particular, there is no mention in Kaszas of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid such as xanthic acid. While Kaszas does mention dithiocarbamate compounds, these are salts of dithiocarbamic acid, i.e.  $\text{NH}_2\text{CS}_2\text{H}$ . Indeed, the present application acknowledges such accelerators on page 2, line 28 of the description. As will be appreciated, dithiocarbamic acid ( $\text{NH}_2\text{CS}_2\text{H}$ ) is quite different from dithiocarbonic acid (carbonic acid is  $\text{H}_2\text{CO}_3$ ) and Kaszas is silent regarding polysulphide compounds derived from a substituted dithiocarbonic acid, for example diisopropyl xanthogen polysulphide.

For the sake of completeness it is also pointed out that there is no mention in

Appl. No. 10/507,214  
Amendment dated: February 5, 2009  
Reply to Final Rejection of: November 28, 2007

Kaszas of a seal for a valve for a pharmaceutical dispensing device (notwithstanding that the crosslinking system recited in the claims of the present application is neither taught nor suggested by Kaszas). Furthermore, Kaszas is not concerned with a valve for use in a pharmaceutical dispensing device (as claimed in claim 20), or a pharmaceutical dispensing device (as claimed in claims 21 and 22), or a dispensing apparatus for dispensing pressurised fluid (as claimed in claims 23 to 27).

In the Official Action it is urged that Whitby teaches providing accelerators for the vulcanization of rubber such as polysulphides substituted dithiocarbonic acid or derivatives thereof such as xanthic acids having isopropyl groups with sulfur for the purpose of providing a rubber product with better properties that can be prepared at lower temperatures. At the outset, Applicants wish to note that this is a 1927 patent which is to provide a new and improved class of accelerators for the vulcanization of rubber which will give to the finished rubber product excellent physical properties, high tensile strength, rapidity of the vulcanization at lower temperatures and related properties.

As stated at page 2 of the patent these products when incorporated into a rubber mix, especially when an amine of the aniline type is also present, greatly accelerate the vulcanization of rubber, increase the tensile strength of the rubber and impart other desirable qualities. Example I shows that this product of the invention is mixed with 100 parts by weight of smoked sheet which is a rubber and clearly, there is no suggestion in this reference in using the accelerator in a valve seal in accordance with the presently claimed invention. This is particularly true in view of the results achieved by the presently claimed invention as evidenced by the data contained in the present specification, see for example page 16 and the figures demonstrating the unique combination of properties exhibited by the presently claimed invention as noted above. Applicants also most respectfully direct the Examiner's attention to MPEP § 2145 wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification. Accordingly, it is most respectfully

Appl. No. 10/507,214  
Amendment dated: February 5, 2009  
Reply to Final Rejection of: November 28, 2007

requested that this rejection be withdrawn.

The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Chan et al, in view of Whitby, Kaszas et al. and Simons et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the previously cited references and the following comments.

Simons relates to a method of making gasketed closure elements for pressurized aerosol containers. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Simons is also not concerned with seals/valves for use in a pharmaceutical dispensing device. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Chan et al, in view of Whitby, Kaszas et al. and Stevenson et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the previously cited references and the following comments.

Stevenson relates an article such as an automobile component, for example a tire. An aircraft tire is specifically mentioned. Stevenson is plainly not concerned with seal and valves for use in a pharmaceutical dispensing device. There would therefore be no motivation for one skilled in the art to look to this reference when faced with the present invention and therefore it is most respectfully requested that this rejection be withdrawn.

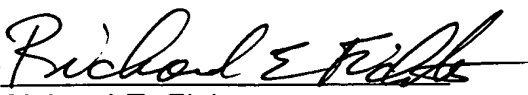
The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Chan et al. in view of Whitby, Kaszas et al. and Blok et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the previously cited references and the following comments.

Appl. No. 10/507,214  
Amendment dated: February 5, 2009  
Reply to Final Rejection of: November 28, 2007

Blok relates to EPDM and EPR-based rubber compositions which are vulcanized with peroxide together with a specified combination of sulfur and acrylate co-agents. However, a requirement of claim 1 of the present application is that the cross-linking agent is free of peroxide curing agents. This means that Blok teaches away from the present invention and cannot render the claims obvious. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The comments in item 10. On page 7 of the rejection are noted and specifically traversed. That is, the statement that, "Furthermore, the known method of polymerizing rubber is the same whether it is for a dispenser or a gasket since the polymers are the same and react in the same manner no matter what the intended use may be" is traversed. Clearly one of ordinary skill in the art would appreciate that there are numerous parameters which need to be considered in determining what goes into the composition and the ultimate use of the composition. There is no teaching in the reasons alone or in combination which would lead one of ordinary skill in the art to the presently claimed invention, especially in view of the results shown in the present application. In view of the above comments, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,  
BACON & THOMAS, PLLC

By   
Richard E. Fichter  
Registration No. 26,382

625 Slaters Lane - 4th Floor  
Alexandria, Virginia 22314  
Phone: (703) 683-0500  
Facsimile: (703) 683-1080  
REF:cjw  
reqreconsider.wpd  
February 5, 2009